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10/806,121	03/23/2004	Wilfred A. Keller	S&B-C409	2116

7590 04/09/2007  
George A. Loud, Esquire  
BACON & THOMAS  
Fourth Floor  
625 Slaters Lane  
Alexandria, VA 22314-1176

EXAMINER
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FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/806,121

Applicant(s)

KELLER ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 1-23,28-35,40-44,49-51 and 56-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-27,36-39,45-48 and 52-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Restriction/Election***

Applicant's election without traverse of Group II in the reply filed on 10 January 2007 is acknowledged.

Claims 1-23, 28-25, 40-44, 49-51 and 56-58, drawn to non-elected inventions, are hereby WITHDRAWN. Claims 24-27, 36-39, 45-48 and 52-55 are examined in the following Office action.

Claims 24, 36, 45, 52 and their dependents are objected to as being dependent upon non-elected claims. Applicant is requested to amend these claims to incorporate the subject matter of the claims on which they depend.

***Specification Objections***

The first paragraph of the specification, as added by the preliminary amendment of 23 March 2004, should be amended to indicate the current status of the parent patent application. The following amendment would remove this objection:

In the paragraph added to page 1 of the specification by the preliminary amendment of 23 March 2004, line 2, the phrase "allowed. United States Patent Application Serial No. 09/886,207" was replaced with:

---now U.S. Patent 6,753,459, which---

All specification amendments should comply with 37 CFR 1.121(b).

The paper copy of the Sequence Listing of 23 March 2004 is objected to for its omission of the application numbers of the U.S. parent and the U.S. provisional applications. See the first page of the Computer Readable Format of the Sequence Listing, where this information is provided.

***Indefiniteness***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45-48 are indefinite in their recitation of "or a related derivative" (in claim 40, on which they depend), as the degree of relatedness or structural similarity is unclear. Deletion of the phrase would obviate this rejection.

Claims 45-48 are also indefinite in their recitation of "the phenotype" in claim 40, which lacks antecedent basis.

***Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-27, 36-39, 45-48 and 52-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a genetic construct comprising any conditionally lethal gene of any sequence and from any organism, including "oncogene 2" of any

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sequence and from any organism, which genes encode any protein or RNA of any sequence and any function. The claims are also drawn to transformed plant cells and plants containing those genetic constructs, and methods of use of the genetic constructs.

In contrast, the specification only provides guidance for a genetic construct comprising the oncogene 2 coding sequence from *Agrobacterium tumefaciens* which encodes the enzyme indoleacetamide hydrolase (IAMH). No guidance is provided regarding the identification, isolation or characterization of any other conditionally lethal gene from any species and of any sequence, or any other "oncogene 2" from any species and of any sequence, each encoding any other product of any sequence or function.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

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A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in *Federal Register*/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

***Enablement***

Claims 24-27, 36-39, 45-48 and 52-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a genetic construct comprising a gene encoding indoleacetamide hydrolase (IAMH) including the *Agrobacterium tumefaciens* oncogene 2 coding region, and plants transformed therewith; does not reasonably provide enablement for claims broadly drawn to a genetic construct comprising any conditional lethal gene including any "oncogene 2" from any species and of any sequence, encoding any protein or RNA of any sequence or function, which somehow function as conditionally lethal genes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a genetic construct comprising any conditionally lethal gene of any sequence and from any organism, including "oncogene 2" of any sequence and from any organism, each encoding any protein or RNA of any sequence and function. The claims are also drawn to transformed plant cells and plants containing those genetic constructs, and methods of use of the genetic constructs, including topical chemical application of plants transformed therewith or exposure of transformed plant cells to activating chemicals in a culture medium.

In contrast, the specification only provides guidance for a genetic construct comprising the oncogene 2 coding sequence from *Agrobacterium tumefaciens* which encodes IAMH. No guidance is provided regarding the identification, isolation or

characterization of any other conditionally lethal gene from any species and of any sequence, or any other "oncogene 2" from any species and of any sequence, each of which encodes any other product of any sequence or function which somehow act as conditionally lethal genes. In addition, no guidance is provided regarding the evaluation of any non-exemplified gene construct for its ability to cause a reversible or sub-lethal conditional lethal phenotype.

The use of oncogenes to cause a conditional lethal phenotype is unpredictable. Smigocki et al teach that plant transformation with a genetic construct comprising the *Agrobacterium tumefaciens* oncogene 4 sequence (*ipt* gene) ligated to a strong constitutive promoter resulted in increased shooting and cell culture proliferation (see, e.g., page 5131, Abstract), rather than any type of lethality. Medford et al teach that the expression of a genetic construct comprising a heat-inducible heat shock promoter ligated to the *ipt* gene unpredictably did not change whether or not the heat shock promoter was actually induced (see, e.g., page 403, Abstract).

Plant cell transformation with non-exemplified oncogenes which are subsequently negated, for the obtention of morphologically normal whole plants from transformed tumor cells which uniformly retain desired transgenes encoding traits of interest, is unpredictable. Ebinuma et al (2000) teach that several of the oncogenes of the T-DNA region have unknown function (see, e.g., page 26, bottom two lines), so that the use of only these genes would not be likely to cause the the sub-lethal phenotype of claim 29, upon which claims 36-39 depend. Ebinuma et al (2000) also teach that the use of *rol* genes from *Agrobacterium rhizogenes* as the oncogenes resulted in the



recovery of mostly morphologically abnormal plants even after the rol gene region was excised, and that chimeric plants not uniformly containing another trait-encoding gene were obtained (see, e.g., page 32, bottom paragraph; page 33, Figure 5 and top paragraph). Ebinuma et al (2001) also teach the disadvantages of the *Agrobacterium rhizogenes*-derived rol genes, and that another oncogene, the tms2 gene, failed to repeatably cause the retention of another trait-encoding gene (see, e.g., page 110, paragraph bridging the columns; page 111, column 2, first full paragraph).

The use of topical plant application of chemicals to induce conditionally lethal genes is unpredictable. See, e.g., Kriete et al, page 815, column 1, to paragraph, who teach that most chemicals which are allegedly non-toxic precursors of toxins either are in fact phytotoxic or do not persist in the field environment, wherein the precursors when applied to plants transgenic for an enzyme-encoding gene are able to be converted into the toxic form, thus effecting a conditional lethal phenotype. See also the instant specification, page 14, bottom paragraph; page 15, top paragraph; page 28, middle paragraph; where it is taught that most chemically-activatable conditional lethal genes have the disadvantage that they lead to cell death and plant lethality, thus preventing the recovery of a desired plant for further breeding, and that the *Agrobacterium tumefaciens* oncogene 2 encoding IAMH is unique in its ability to effect a controllable, sub-lethal phenotype.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify, isolate or evaluate a multitude of non-exemplified conditionally lethal genes

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including non-*Agrobacterium tumefaciens* oncogene 2. Undue experimentation would have also been required to evaluate their ability to controllably and effectively cause conditional lethality in plants transformed therewith, particularly when plants or plant cells are exposed to activating chemicals topically or in tissue culture

**Anticipation.**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-27 and 36-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Jorgensen (U.S. Patent 5,278,057).

The claims are broadly drawn to a genetic construct comprising a coding sequence encoding a conditionally lethal gene product, ligated to a promoter which is expressible in at least one plant cell, or is expressible in response to a chemical stress, or is tissue-specific, which construct further comprises a second gene which confers a measurable change in phenotype, which encodes a protein; and are also broadly drawn to vectors and transformed Brassica plants containing the construct, and to methods of their use involving topical application of the transformed Brassica plants with the chemical substrate of the conditionally lethal gene product.

Regarding claims 25 and 37, most currently cultivated Brassica plants have oil content with “altered” composition relative to the initial wild relatives of said cultivated plants, particularly with regard to glucosinolate content or saturated fatty acid content,

as observed in the canola-type varieties. Regarding claims 26 and 38, "high" and "low" are relative terms, so that any cultivated Brassica variety may have higher oleic acid and lower linoleic acid than some other variety. Regarding claims 27 and 39, any Brassica variety may be a "derivative" of variety AG-019, since the degree of derivation or steps involved in said derivation are not specified. Thus claims 27 and 39 read on products of a multitude of generations of outcrossing to non-AG-019, even if AG-019 were one of the parents of the initial cross.

Jorgensen teaches a genetic construct comprising oncogene 2 from *Agrobacterium* (otherwise known as the *iamH* gene which encodes indoleacetamide hydrolase) under the control of a constitutive promoter and said genetic construct further comprising a kanamycin resistance gene, and methods for plant transformation therewith and activation of the conditionally lethal (or sub-lethal) phenotype by topical application with naphthalene acetamide, wherein visual symptoms of conditional lethality or sublethality including epinasty and leafroll were observed (see, e.g., columns 11 and 23-27). Brassica transformation is specifically taught in column 7, lines 47-59; and in claims 1, 9-12 and 14

Claims 24-27 and 36-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Fabijanski et al (U.S. Patent 5,426,041).

Fabijanski et al teach a genetic construct comprising oncogene 2 under the control of a constitutive promoter or pollen-specific L4 promoter or inducible promoter, and further comprising a kanamycin resistance gene, and methods for plant transformation therewith and activation of the conditionally lethal (or sub-lethal)

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phenotype by topical application with naphthalene acetamide (see, e.g., columns 5-9, 15-20, 25-27, 29-30 and claims 1-6). Brassica transformation is specifically taught in column 14, line 67 through column 15, line 32; column 26; lines 24-42; and column 30, lines 21-25.

### **Obviousness**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-27, 36-39, and 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dotson et al (U.S. Patent 5,254,801) in view of Moloney et al (US 5,750,871).

Claims 36-39 are drawn to the use of a conditionally lethal gene to remove a plant from the environment via topical application of a Brassica plant transformed with

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the conditionally lethal gene. Claims 45-48 are drawn to a method of culturing a transformed Brassica seed or embryo with any "oncogene 2" from any source and of any sequence, wherein said transformed seed or embryo when cultured on a "related derivative" of indoleacetamide exhibits "the phenotype". Any gene that causes or inhibits cell division on culture medium may be considered an unspecified "oncogene 2". Any auxin in a tissue culture medium, including NAA or IAA, may be considered some type of "derivative" of indoleacetamide. Any phenotype may be considered "the phenotype", including cell division or lack thereof on tissue culture medium.

Dotson et al teach a genetic construct comprising the conditionally lethal phosphonate monoester (peh) gene under the control of a constitutive enhanced CaMV 35S promoter for expression throughout the entire plant or under the control of a tapetum-specific p127a promoter, wherein said genetic construct further comprises a kanamycin resistance gene encoding a protein which confers the measurable phenotype of antibiotic resistance to the plant cell; and also teach vectors and transformed plants comprising the construct, wherein topical application of the chemical glycerol glyphosate, which may itself be considered a chemical stressor due to its slight toxicity, allows the production of the herbicide glyphosate in the transformed plant cells which express the *peh* gene (see, e.g., columns 1, 2, 4, 5, 7-9, 22-24 and 27-31; Figures 8-10).

Dotson et al do not explicitly teach Brassica plants transformed with a conditionally lethal gene or the use of the conditionally lethal gene to remove a whole plant from the environment.

Dotson et al suggest the use of inducible promoters, and the use of the conditionally lethal gene to remove undesired individuals, and also teach the use of the conditionally lethal gene as a selection means for cells cultured on a medium containing a chemical which is converted into a toxic substance by the product of the conditionally lethal gene expressed under the control of the constitutive enhanced CaMV 35S (see, e.g., column 5, lines 13-25; column 9, lines 20-23; column 29, line 11 through column 30, line 47). Dotson et al also suggest the transformation of Brassica with the conditionally lethal gene, including "canola" varieties with "altered oil composition" relative to non-canola varieties (see, e.g., column 27, lines 25-29).

Moloney et al teach Brassica transformation and whole transformed Brassica plants, wherein a variety of Brassica species including rapeseed (which include canola varieties) may be transformed, wherein the plants are obtained by selecting transformed cells on a selection medium containing a chemical, wherein the transformed cells may be additionally transformed with genes conferring male sterility, altered oil composition, etc (see, e.g., column 5, lines 21-47; column 6, lines 20-38; column 7, lines 6-10; column 14, line 57 through column 18, line 28).

It would have been obvious to one of ordinary skill in the art to utilize the genetic construct comprising a conditionally lethal gene as taught by Dotson et al, and to modify that construct by incorporating Brassica transformation taught by Moloney et al, as suggested by Dotson et al. It would have also been obvious to utilize the conditionally lethal gene as a negative selection marker for an embryo or a whole plant, as suggested by Dotson et al for cultured cells, given the recognition by those of ordinary

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skill in the art of the ecological advantages of eliminating superfluous transgenic plants from the environment, and given the recognition that the constitutive promoter utilized by Dotson et al would function in all cells of a whole plant.

Claims 24-27 and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/40179 (PIONEER) in view of Moloney et al (US 5,750,871).

PIONEER teaches a genetic construct comprising the *iamH* gene ligated to a seed-specific promoter such as the phaseolin or napin promoters, the pollen-specific *Brassica* L4 ("Bp 4") promoter, the heat- or light- or chemical-inducible heat shock, GST II, or CAB promoters, respectively; said genetic construct further comprising a PAT gene conferring resistance to the herbicide bialaphos; vectors and plants transformed therewith (see, e.g., columns 9, 12-15 and 19-21). PIONEER also suggests *Brassica* plants to be transformed and utilized in their method (see, e.g., page 8, lines 29-31; page 15, lines 10-17; and page 16, lines 14-20).

PIONEER does not explicitly teach *Brassica* plants transformed with the *iamH* gene.

Moloney et al teach transformed *Brassica* plants, as discussed above.

It would have been obvious to one of ordinary skill in the art to utilize the method of plant transformation with conditionally lethal gene and another gene of interest as taught by PIONEER, and to modify that method by incorporating the *Brassica* transformation method taught by Moloney et al, as suggested by PIONEER.

Claims 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al (U.S. Patent 5,426,041) in view of Dotson et al (U.S. Patent 5,254,801).

The claims are drawn to the use of the *Agrobacterium tumefaciens* oncogene 2 conditionally lethal gene as a marker gene for identifying transformed Brassica seeds or embryos.

Fabijanski et al teach Brassica plant transformation with *Agrobacterium tumefaciens* oncogene 2, as discussed above, but do not teach the use of the gene as a selectable marker for transformed seeds or embryos.

Fabijanski et al also teach the use of the oncogene 2 as a selectable marker gene for transformed pollen grains cultured on a medium containing the substrate of the enzyme (see, e.g., column 29, line 30 through column 30, line 57).

Dotson et al teach the use of a conditionally lethal gene as a marker, as discussed above.

It would have been obvious to one of ordinary skill in the art to utilize the genetic construct comprising the *Agrobacterium tumefaciens* oncogene 2 taught by Fabijanski et al as a selectable marker for Brassica, as suggested by Dotson et al. Furthermore, it would have been obvious to utilize the Brassica seed or embryo tissue as the tissue to be assayed, given the successful teaching of Fabijanski et al of the use of the oncogene 2 as a marker gene in other plant organs, and given the recognition by those of ordinary skill in the art that choice of explant or tissue type to be assayed for transformation would have been the optimization of process parameters.

Claims 25-27, 37-39 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dotson et al (US 5,254,801) in view of Moloney et al (US 5,750,871), further in view of Sernyk et al (US 5,965,755).



For the purpose of this rejection, the claims are being interpreted as being drawn to transformed Brassica plants of the cultivar AG-019.

Dotson et al in view of Moloney et al teach methods for making and using Brassica plants transformed with a conditionally lethal gene as discussed above, but do not teach transformation of the high oleic and low linoleic cultivar AG-019.

Sernyk et al teach the Brassica cultivar AG-019 which produces seed containing oil with high oleic acid levels and low linoleic acid levels, wherein such oil has increased stability and health benefits; and also suggest the genetic modification and/or tissue culture of said variety to incorporate other desirable traits or genes (see, e.g., column 2, lines 10-34; column 3, line 12 through column 4, line 12; and column 13, lines 21-46).

It would have been obvious to one of ordinary skill in the art to utilize the methods for making and using transformed Brassica plant containing a conditionally lethal gene as taught by Dotson et al in view of Moloney et al, and to modify those methods by incorporating the cultivar AG-019 taught by Sernyk et al, as suggested by Sernyk et al.

Claims 25-27 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al (US 5,426,041), in view of Sernyk et al (US 5,965,755).

For the purpose of this rejection, the claims are being interpreted as being drawn to transformed Brassica plants of the cultivar AG-019.

Fabijanski et al teach methods for making and using Brassica plants transformed with a conditionally lethal gene as discussed above, but do not teach transformation of the high oleic and low linoleic cultivar AG-019.

Sernyk et al teach the Brassica cultivar AG-019 which produces seed containing oil with high oleic acid levels and low linoleic acid levels, wherein such oil has increased stability and health benefits; and also suggest the genetic modification and/or tissue culture of said variety to incorporate other desirable traits or genes, as stated above.

It would have been obvious to one of ordinary skill in the art to utilize the methods for making and using transformed Brassica plant containing a conditionally lethal gene as taught by Fabijanski et al, and to modify those methods by incorporating the cultivar AG-019 taught by Sernyk et al, as suggested by Sernyk et al.

Claims 25-27 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen (US 5,278,057), in view of Sernyk et al (US 5,965,755).

For the purpose of this rejection, the claims are being interpreted as being drawn to transformed Brassica plants of the cultivar AG-019.

Jorgensen teaches methods for making and using Brassica plants transformed with a conditionally lethal gene as discussed above, but do not teach transformation of the high oleic and low linoleic cultivar AG-019.

Sernyk et al teach the Brassica cultivar AG-019 which produces seed containing oil with high oleic acid levels and low linoleic acid levels, wherein such oil has increased stability and health benefits; and also suggest the genetic modification and/or tissue culture of said variety to incorporate other desirable traits or genes, as stated above.

It would have been obvious to one of ordinary skill in the art to utilize the methods for making and using transformed Brassica plant containing a conditionally lethal gene as taught by Jorgensen, and to modify those methods by incorporating the cultivar AG-019 taught by Sernyk et al, as suggested by Sernyk et al.

Claims 25-27 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/40179 (PIONEER) in view of Moloney et al (US 5,750,871), further in view of Sernyk et al (US 5,965,755).

For the purpose of this rejection, the claims are being interpreted as being drawn to transformed Brassica plants of the cultivar AG-019.

PIONEER in view of Moloney et al teach methods for making and using Brassica plants transformed with a conditionally lethal gene as discussed above, but do not teach transformation of the high oleic and low linoleic cultivar AG-019.

Sernyk et al teach the Brassica cultivar AG-019 which produces seed containing oil with high oleic acid levels and low linoleic acid levels, wherein such oil has increased stability and health benefits; and also suggest the genetic modification and/or tissue culture of said variety to incorporate other desirable traits or genes, as stated above.

It would have been obvious to one of ordinary skill in the art to utilize the methods for making and using transformed Brassica plant containing a conditionally lethal gene as taught by PIONEER in view of Moloney et al, and to modify those methods by incorporating the cultivar AG-019 taught by Sernyk et al, as suggested by Sernyk et al.

Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al (U.S. Patent 5,426,041) in view of Dotson et al (U.S. Patent 5,254,801), further in view of Sernyk et al (US 5,965,755).

For the purpose of this rejection, the claims are being interpreted as being drawn to transformed Brassica plants of the cultivar AG-019.

Fabijanski et al in view of Dotson et al teach methods for making and using Brassica plants transformed with a conditionally lethal gene as discussed above, but do not teach transformation of the high oleic and low linoleic cultivar AG-019.

Sernyk et al teach the Brassica cultivar AG-019 which produces seed containing oil with high oleic acid levels and low linoleic acid levels, wherein such oil has increased stability and health benefits; and also suggest the genetic modification and/or tissue culture of said variety to incorporate other desirable traits or genes, as stated above.

It would have been obvious to one of ordinary skill in the art to utilize the methods for making and using transformed Brassica plant containing a conditionally lethal gene as taught by Fabijanski et al in view of Dotson et al, and to modify those methods by incorporating the cultivar AG-019 taught by Sernyk et al, as suggested by Sernyk et al.

### **Conclusion**

Claims 52-55 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest the use of an auxin transport inhibitor in a selection medium for obtaining whole transformed plants which comprise an oncogene including

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oncogene 2 from *Agrobacterium tumefaciens*., as stated in parent application number 09/886,207, now US Patent 6,753,459.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 31, 2007

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

